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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,573	03/22/2001	Hector F. DeLuca	1256-00721	9707

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/815,573	DELUCA ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's response filed on January 3, 2003 in Paper No. 14. Currently, claims 1-7 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (4,338,312 and 4,110,446, of record) for reasons of record stated in the Office Action October 2, 2002.

DeLuca et al. (4,338,312) discloses that an oral administration to a dairy cow of a composition comprising a 1α-hydroxylated vitamin D such as 1α-hydroxy vitamin D_3 and 1α,25-dihydroxyvitamin D_3, within instant claim, with low phosphorus is useful in a method of treatment and prophylaxis for milk fever in dairy cattle. See '312 abstract, col.2 lines 54-65, col.3 Example, and claims 1, 3, and 10; '446 abstract, col.2 lines 37-49, col.5 lines 10-19, and claims 1, 3, and 5. DeLuca et al. also discloses the effective amounts of 1α-hydroxy vitamin D_3 i.e., 0.3-0.5 mg, and 1α,25-dihydroxyvitamin D_3 i.e., 2-4 mg, dissolved in corn oil to be administered. See col.2 lines 36-65. DeLuca et al. further discloses that administering 1α-hydroxylated vitamin D such as 1α-hydroxy

vitamin D_3 with the diet containing low phosphorus was maintained throughout the parturition portion in the experiment. See col.3 lines 15-19. DeLuca et al. also discloses that the 1α-hydroxylated vitamin D composition therein can be applied topically in a suitable vehicle (see col.4 lines 1-5).

DeLuca et al. (4,110,446) discloses that an oral administration to a dairy cow of a composition comprising a 1α-hydroxylated vitamin D such as 1α,25-dihydroxyvitamin D_3, within instant claim, is useful in a method of treatment and prophylaxis for milk fever in dairy cattle. See abstract, col.2 lines 37-49, col.5 lines 10-19, and claims 1 and 6. DeLuca et al. also discloses that the range of the effective amounts of 1α,25-dihydroxyvitamin D_3 is 200-400 μg, dissolved in corn oil to be administered. See col.2 lines 36-65. DeLuca clearly teaches that 1α-hydroxylated vitamin demonstrates a marked ability to prevent the fall in serum calcium and phosphorus levels in a dairy cow (see col.5 lines 11-17).

DeLuca et al. do not expressly disclose "feeding as part of a daily diet" an effective amount of a 1α-hydroxylated vitamin D herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to motivated to feed as part of a daily diet an effective amount of a 1α-hydroxylated vitamin D herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to feed as part of a daily diet an effective amount of a 1α-hydroxylated vitamin D herein because an oral administration to a dairy cow of an effective amount of a 1α-hydroxylated vitamin D herein is known in the prior art.

Moreover, an effective amount of a 1α-hydroxylated vitamin D herein is known to be administered with a cow diet containing low phosphorus throughout the parturition portion (milk fever). Further, feeding a known oral composition which is also known to administered with a cow diet, as part of daily diet to a dairy cow is considered well within conventional skills in animal (food and nutritional) science or industry, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Applicant's remarks filed January 3, 2003 in Paper No. 14 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action dated October 2, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicants argue that the prior art does not teach that the feed therein contains about 0.3% by weight or less of an inorganic phosphorus supplement as well as an effective amount of 1α-hydroxylated vitamin D. However, as discussed in the previous Office Action, DeLuca discloses that the composition comprising a 1α-hydroxylated vitamin D such as 1α-hydroxy vitamin D_3 and 1α,25-dihydroxyvitamin D_3, with low phosphorus is known to be useful in a method of treatment and prophylaxis for milk fever in dairy cattle. Moreover, the effective amounts of 1α-hydroxy vitamin D_3 i.e., 0.3-0.5 mg, and 1α,25-dihydroxyvitamin D_3 i.e., 2-4 mg or 200-400 μg, within the instant claims, are known to be administered in the treatment of milk fever in dairy cattle according the DeLuca.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, one of ordinary skill in the art would have been motivated to optimize the effective amount of an inorganic phosphorus to about 0.3% by weight or less, or optimize the known effective amounts of 1α-hydroxy vitamin D_3 and 1α,25-dihydroxyvitamin D_3 in the composition for the method of maintaining milk production in a dairy cow based on the disclosure of DeLuca to achieve a beneficial effect, which is considered well within the skill of artisan, involving merely routine skill in the art. Moreover, the instant claim 1 is limited to "feeding a feed that contains about 0.3% by weight or less of an inorganic phosphorus supplement". Thus, the claim may be read as 0.3% to 0% of an inorganic phosphorus supplement employed herein. Further, administering 1α-hydroxylated vitamin alone to a dairy cow is known to be useful to prevent the fall in serum calcium and phosphorus levels in a dairy cow according to DeLuca '446.

Again Applicants' argument regarding "in the dry period" in DeLuca '312 patent are not found convincing. As discussed in the previous Office Actions, DeLuca clearly discloses the method for prophylactically treating dairy cow for parturient paresis comprising administering the instant compounds (see claims 1 and 3). Parturient paresis (milk fever) is known to be a metabolic disease of dairy cows including lactating dairy cows resulting from parturition and the initial formation of milk according to DeLuca (col.1 lines 8-15). Moreover, DeLuca ' 446 patent clearly discloses that the results in these tables (see Tables 2 and 3) are from the testing on the administration

1α,25-dihydroxyvitamin D_3 to cows during and post-calving period since one of ordinary skill in the art would clearly recognize that "lactation no." would be the number of the offspring born by cow (as admitted by Applicants in the response filed May 24, 2002 at page 6) that is in a lactating period. Thus, the scope of DeLuca's method nowhere is limited to dairy cows "in the dry period".

Applicants' arguments regarding "lactation no." in Tables 2 and 3 in DeLuca ' 446 patent are not found persuasive since DeLuca clearly discloses that the results in these tables are from the testing on the administration 1α,25-dihydroxyvitamin D_3 to cows during and post-calving period. Therefore, one of ordinary skill in the art would clearly recognize that "lactation no." would be the number of the offspring born by cow (as admitted by Applicants in the response page 6) that is in a lactating period.

Further, Applicant's arguments and results regarding to testing the instant vitamin D compounds and low phosphorus in the specification at pages 13-17 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive. The results of Tables 2-4 at pages 15-17 showing the effects of the instant vitamin D compounds are clearly expected to benefit the instant claimed method of maintaining the milk production and increasing phosphorus uptake in a dairy cow since 1α-hydroxylated vitamin is known to process a marked ability to prevent the fall in serum calcium and phosphorus levels in a dairy cow according to DeLuca. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Therefore, the evidence presented in

specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 21, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

2/24/03